

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS,)
U.S.A., INC.,)
)
)
Plaintiff,) C.A. No. 19-2216-RGA
)
)
v.)
)
MYLAN PHARMACEUTICALS,)
INC.,)
)
Defendant.)

Tuesday, January 21, 2020
10:18 a.m.
Courtroom 6A

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE RICHARD G. ANDREWS
United States District Court Judge

APPEARANCES:

DRINKER, BIDDLE & REATH, LLP
BY: FRANCIS DIGIOVANNI, ESQ.
BY: THATCHER A. RAHMEIER, ESQ.

- and -

HAUG PARTNERS, LLP
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Counsel for the Plaintiff

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3 MORRIS JAMES, LLP
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12 GOODWIN PROCTOR, LLP
13 BY: SAMUEL SHERRY, ESQ.
BY: ELIZABETH HOLLAND, ESQ.
BY: CHRISTINE LAROCHELLE, ESQ.

14 Counsel for the Intervenor
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1 THE COURT: All right. Please be
2 seated, everyone. Sorry for the delay. All
3 right. So this is the motion to intervene and
4 the primary injunction in Takeda versus Mylan,
5 civil action number 19-2216. So for plaintiff,
6 Mr. DiGiovanni, how are you?

7 MR. DiGIOVANNI: Very well, Your
8 Honor. Thank you. So let me introduce my
9 counsel. Co-counsel. For the record, Frank
10 DiGiovanni from Drinker, Biddle & Reath.
11 Thatcher Rahmeier, my associate, is here also.
12 From the Haug Partners LLP, Mr. Porter Fleming,
13 who is going to be making today's argument,
14 Jonathan Herstoff and Camille Turner. And let
15 me introduce the Takeda representatives in-house
16 counsel, Mark Buonaiuto, as well as David
17 Banchil. Thank you, Your Honor.

18 THE COURT: Okay. Thank you. So
19 for defendant. Mr. Townsend.

20 MR. TOWNSEND: Good morning, Your
21 Honor. Bryan Townsend from Morris James on
22 behalf of the defendant. With me at counsel
23 table we have Michael Sommer, who will be making
24 the arguments today, as well as his colleagues

1 Jessica Margolis and Sheryl Shapiro Bassin. We
2 also have behind the table we have Doug Miner
3 and Preston Pieratorra.

4 THE COURT: Okay. Thank you. For
5 the proposed intervenor, Par Pharmaceuticals out
6 there. Ms. Keller.

7 MS. KELLER: Good morning, Your
8 Honor. Karen Keller from Shaw Keller on behalf
9 of Par Pharmaceuticals. With me today from
10 Goodwin Proctor are Elizabeth Holland, Sam
11 Sherry and Christine Larochele. And also from
12 Par Pharmaceuticals, Gina Jackarelli.

13 THE COURT: All right. What I
14 thought was we'd deal with the motion to
15 intervene first. And so Ms. Holland, that's
16 you.

17 MS. HOLLAND: Yes, Your Honor.
18 Actually, Mr. Sherry is going to argue the
19 motion to intervene.

20 THE COURT: Okay. Mr. Sherry. I
21 should say I have read all the briefs, I think,
22 that have been submitted, including a couple
23 that are attached as exhibits to things. I
24 hadn't unsealed them yet. Also, I would say

1 there's no need to say anything here in court
2 that anybody is going to need to be asking me to
3 seal later on, so bear that in mind when you're
4 speaking.

5 MR. SHERRY: Indeed. Thank you,
6 Your Honor. So Par's motion to intervene should
7 be granted either as of right or permissively
8 under rule 24. And I just want to note on the
9 top that while Takeda poses what I'll describe
10 as a lead objection regarding standing on the
11 patent claims, resolving that particular issue
12 isn't necessary to resolve Par's intervention
13 motion.

21 MR. SHERRY: Well, we think that
22 the collection of agreements, the settlement
23 agreement, the license agreement and the
24 distribution agreement are intended to create an

1 exclusive authorized generic and that the intent
2 and effect of that agreement is sufficient for
3 us to bring standing on the patent claims. But
4 I certainly agree, Your Honor, that that is not
5 what we're resting on as the sole basis for the
6 intervention motion.

7 THE COURT: And do you also, in
8 your complaint in intervention had a complaint
9 for, think it was called intentional
10 interference with contract, right?

11 MR. SHERRY: With contractual
12 relations, that's correct.

13 THE COURT: So the case that you
14 cite in your brief somewhere for the proposition
15 that you actually can make that claim says you
16 have to say that somebody breached a contract
17 with you, but there's nothing in your complaint
18 that says anybody has breached the contract with
19 you, is there?

20 MR. SHERRY: Well, the case law
21 requires either a breach or a cancellation. A
22 breach itself is not a requirement to bring an
23 intentional interference claim.

24 THE COURT: Okay. And do you have

1 a case citation for that?

2 MR. SHERRY: I don't have a case
3 for you at this exact moment, but I can provide
4 one for that.

5 THE COURT: Okay. All right.

6 Well, let's move along here.

7 MR. SHERRY: In any event,
8 intervention is warranted under Par's state law
9 of claims of tortious interference with
10 contractual relations and unfair competition.
11 And I'll address 24(a) first. I'll try to run
12 through the elements quickly, as I'm sure you're
13 aware of them.

14 THE COURT: Yeah, why don't you
15 concentrate on that your interest is not
16 adequately represented by an existing party in
17 the litigation. And I base that on the interest
18 that you have in common is the interpretation of
19 the contract between Takeda and Mylan.

20 MR. SHERRY: Well, the interests
21 that are at stake are a little broader than
22 that. So perhaps I'll address, with your
23 permission, Your Honor, briefly address those
24 and then turn to the representation issue.

THE COURT: Yeah. Go ahead.

2 MR. SHERRY: So Takeda also has an
3 argument, which I'll agree is secondary to the
4 representation argument, but I think this is
5 foundational, regarding its argument that Par is
6 not a party to the Takeda/Mylan contract, but
7 notwithstanding that, Par's interests are at
8 stake here and you can see that if you look at
9 that either broadly or narrowly. Broadly
10 speaking, it's Mylan's unlawful sales that are
11 both the initiating act that presents the main
12 action and are also the cause of damages to Par.
13 And Par has an interest in enjoying the benefits
14 of its contractual relations with Takeda and its
15 contractual relations with its distribution
16 partners and both of those contractual benefits
17 have been damaged and would be damaged further
18 barring a PI from Mylan's launch. And these
19 type of interests, the contractual relation
20 interests and these direct economic interests
21 are the sort of interests that have been deemed
22 sufficient for intervention by the third circuit
23 or in the third circuit. And in particular I'm
24 thinking of, referring to the Chrysler v. U.S.

1 Forest Services case and the Michaels Stores v.
2 Castle Ridge. You can also look at these
3 somewhat more narrowly. There's the contract
4 that Par lost during Mylan's brief launch last
5 year. Mylan's improper contacts with Par's AG
6 customers and again, the same damage that Mylan
7 would do from its launch if it launched again.
8 And each of these things -- each of these harms
9 to Par are specifically named in Takeda's
10 complaint as examples of Mylan's wrongful
11 action. And so for that reason Takeda has
12 brought Par's harm and Par's interests directly
13 into the main action.

14 THE COURT: But isn't Takeda's
15 action breach of contract and patent
16 infringement?

17 MR. SHERRY: Yes. And those are
18 intended to stop -- the entire purpose of that
19 is to stop Mylan's unlawful sales. And in fact,
20 the acts that I just mentioned regarding Mylan's
21 interference with Par's contracts, those are
22 examples of the damage that Mylan is doing in
23 breach of the contract and by infringing the
24 patents at issue.

THE COURT: All right.

2 MR. SHERRY: And so turning to the
3 representation question, there are basically
4 three reasons why Takeda doesn't adequately
5 represent Par's interests here. First, Par and
6 Takeda seek different damages. They're closely
7 related, Your Honor, but they're not actually
8 the same damages.

11 MR. SHERRY: Okay. I'll move on,
12 but I'll just note that Bode Bry v. Strang and
13 Michaels Stores both recognize that a party
14 doesn't represent a potential intervenor if it's
15 seeking a different remedy. The second reason
16 why Takeda doesn't represent --

22 MR. SHERRY: That is correct. I
23 can't speak to whether that alone is sufficient.
24 I think the critical point here is that the end

result that we're attempting to seek are not identical. As in Takeda is seeking X million dollars for its damages and Par is seeking Y million dollars for its damages. They're sort of adjacent to each other because they're both related to harm to the AG market that Par and Takeda share, but they are different pools of money. And if Takeda and Par are successful, Mylan would be paying each of those separately to Takeda and to Par. And so that's the nature in which they're different.

12 THE COURT: Okay.

13 MR. SHERRY: The second reason is
14 that -- and this is clear from the PI briefing,
15 is that Takeda has not presented the court with
16 the harm that is particular to harm -- sorry,
17 that is particular to Par that Par would suffer
18 from Mylan's re-entry into the market.

19 THE COURT: Right. But they
20 have -- yeah. Actually that's right. Yeah.

21 MR. SHERRY: And there's no
22 structured reason why that has to be the case.
23 Obviously Takeda could have presented that
24 information.

1 THE COURT: Probably not for the
2 same reason you couldn't argue the merits
3 because you hadn't seen their contract. They
4 don't know what your -- I mean, there's a gulf
5 between the two of you in terms of what you know
6 about each other.

7 MR. SHERRY: That is fair enough,
8 Your Honor, although Takeda has quite a lot of
9 information regarding Par's sales, because
10 obviously Takeda gets royalties from Par's
11 sales, and so there's reporting as far as that's
12 concerned. I don't claim that Takeda has
13 perfect knowledge on that. That's almost
14 certainly true. The point is that there's
15 particularly harm to Par that is not being
16 represented -- presented to the Court right now
17 or is not absent our intervention, and so sort
18 of regardless of what could happen, there's, in
19 fact, a lack of adequate representation with
20 respect to that particular issue. And then the
21 third basis for a lack of adequate
22 representation is Mylan's defense, because
23 Mylan's defense -- and again, we don't have a
24 completely clear view onto everything that's

1 going on on the merits phase, but from what we
2 can tell, Mylan's defense appears to be that
3 Takeda has, in fact, authorized the launch,
4 authorized their entry into the market. And
5 therefore, in effect, Mylan is saying that to
6 the extent Par is harmed by that, it is Takeda's
7 doing, not Mylan's, because Takeda authorized
8 that. That appears to be the gist of Mylan's
9 defense with respect to Par's issues. And given
10 that, those allegations and that state, Takeda
11 is just not in a position where it can be
12 representing Par's interests if Mylan, the other
13 party in this, is saying that, in fact, it's
14 Takeda is causing the harm not Mylan.

15 THE COURT: Still the Takeda
16 position is Mylan is wrong, they're breaching
17 the contract, which is exactly your position,
18 right?

19 MR. SHERRY: Yes. I would agree
20 that there is -- there is certainly agreement
21 between Takeda and Par with respect to the
22 breach of contract issue. That's correct. But
23 that's --

24 THE COURT: And doesn't that, if

1 Takeda is right, doesn't that resolve -- doesn't
2 that sort of moot your third reason?

3 MR. SHERRY: If Takeda -- sorry,
4 if Takeda is right, then -- and of course we
5 agree that that's the case, then the third
6 reason wouldn't come into effect. But I assume,
7 and I don't think Mylan will disagree with this,
8 that Mylan intends to maintain this position
9 throughout the case.

10 THE COURT: No. That's it. They
11 have a view, Takeda has a view, but Takeda's
12 view is your view.

13 MR. SHERRY: On this particular
14 issue, yes. But there are -- what I'm saying is
15 that there are implications of this argument by
16 Mylan, which is to say that if Mylan is right,
17 then Takeda is in a position where it may be
18 just trying to defend its own interests, not
19 merely agreeing to -- I'm sorry, I'm not saying
20 this very clearly. If Mylan -- since Mylan is
21 presenting this issue, Takeda is in a position
22 where it is not merely arguing the agreed
23 position where Par and Takeda agree that Mylan
24 is simply wrong. It also has some interest in

1 protecting itself from the implications of this
2 argument.

3 THE COURT: Okay. So that's your
4 intervention as of right argument, right?

5 MR. SHERRY: Right. Excuse me,
6 intervention is also warranted in the
7 alternative.

8 THE COURT: Yeah, yeah, let's not
9 bother with that. So let me hear from Mr.
10 Fleming. Thank you, Mr. Sherry.

11 MR. SHERRY: Thank you, Your
12 Honor.

13 MR. FLEMING: Good morning, Your
14 Honor.

15 THE COURT: Hi, Mr. Fleming. How
16 are you?

17 MR. FLEMING: Very good. Thank
18 you. I'll just be very brief. I think reading
19 between the lines of what you just said --

20 THE COURT: Okay, you shouldn't do
21 that.

22 MR. FLEMING: Okay. I won't do
23 that. There is no basis for Par to assert any
24 of the patents in this case. They have no

1 exclusionary rights.

2 THE COURT: You don't need to do
3 that part.

4 MR. FLEMING: Okay. That was the
5 part I was reading.

6 THE COURT: Okay.

7 MR. FLEMING: There is no subject
8 matter jurisdiction and I think I just heard
9 from Mr. Sherry that he agreed that with respect
10 to Takeda's view is your view. And that is
11 correct with respect to Takeda and Par are both
12 seeking the same -- and we cite this Hoots case.
13 We are both seeking that Mylan has breached
14 1.2(d) of the license agreement and we are
15 seeking a preliminary injunction to stop that
16 and that is exactly what Par wants. So we're on
17 the same footing there. Par has no rights under
18 those patents, but in any event we're seeking
19 the same thing. I also heard Mr. Sherry talked
20 about a tortious interference and unfair
21 competition claims, which are state law claims
22 and he went into agreements between Par and its
23 distributors. Those clearly have nothing to do
24 with the complaint that we brought against

1 Mylan. The complaint against Mylan, as Your
2 Honor noted a short while ago, is a breach of
3 contract and patent infringement on 17 orange
4 book patents, so to the extent Par is now
5 arguing for tortious interference and
6 interference of business to come into the case,
7 there is new claims, new facts, new issues that
8 go beyond anything that's in the case. We
9 believe there should be -- that Par should not
10 intervene, period.

11 THE COURT: By the way, do you
12 think the -- and this is a preview of coming
13 attractions, I guess. Do you think the question
14 of interpretation of section 1.2(d) of the
15 contract, is that a question of law?

16 MR. FLEMING: I think it is a
17 question of law. To the extent that the parties
18 will be, at some point, perhaps not at
19 preliminary injunction, asking you to determine
20 that, I think that the at the preliminary
21 injunctions you will have to look at the
22 likelihood of success of one party to prevail at
23 that point. I also think we have to look at the
24 intent of the parties and under the context of

1 how that agreement came to be between Mylan and
2 Takeda and how that resolved an ANDA litigation
3 and how --

4 THE COURT: So are you saying that
5 there's a necessity for extrinsic evidence?

6 MR. FLEMING: I think the language
7 of 1.2(d), as I'm interpreting it, is
8 unambiguous. And no, I'm not looking for
9 extrinsic evidence or parole evidence. I think
10 it is interesting, as you'll hear from Mylan,
11 they have a different interpretation. We have
12 competing interpretations and that's an
13 interesting question whether competing
14 interpretation in and of itself makes them
15 ambiguous or not.

16 THE COURT: There's a zillion
17 cases that say that's not the case, otherwise
18 every contract would be ambiguous if people were
19 arguing about it.

20 MR. FLEMING: Correct. So our
21 position is unambiguous, Mylan has breached
22 1.2(d) because they have not satisfied that all
23 the patents that were asserted were adjudicated.

24 THE COURT: Okay. And basically

1 in terms of this motion to intervene, the case
2 that you think is more -- is your best case is
3 this Hoots case, right?

4 MR. FLEMING: Well, I think --
5 yes, Your Honor. Par and Takeda are aligned to
6 the extent that A, they're saying Mylan has
7 breached our agreement. That's the Takeda/Mylan
8 agreement. Par is not even a party to that
9 agreement. And to the extent they're asserting
10 patent infringement, I looked at their complaint
11 in intervention, it's basically a copy job of my
12 complaint, the same 17 patents and a hundred
13 plus paragraphs that are exactly the same. We
14 are aligned.

15 THE COURT: Okay. Do you have any
16 opinion on the question I asked Mr. Sherry with
17 whether intentional interference with contract
18 requires a breach or can it just be a quote
19 termination.

20 MR. FLEMING: I don't have an
21 opinion, but I will say it's not in my case,
22 it's not in the Takeda/Mylan case, so I think
23 that highlights the point of a different issue
24 that's really not part of our case.

1 THE COURT: That's a fair
2 response. Okay. Is there anything else you
3 want to tell me?

4 MR. FLEMING: No, thank you, Your
5 Honor.

6 THE COURT: Mr. Sherry, is there
7 anything further you want to say?

8 MR. SHERRY: Yes. Just a few
9 points, Your Honor. One, the case that I was
10 referring to that I didn't have a cite for you
11 when I was up here before, that is ASDI
12 Incorporated v. Beard Research and the cite is
13 11 A 3d --

14 THE COURT: Is that in the
15 briefing?

16 MR. SHERRY: No, I don't believe
17 it's in the briefing, Your Honor.

THE COURT: Okay. What is it?

19 MR. SHERRY: 11 A 3d 749 and the
20 pin cite is 751 and that's Delaware Supreme
21 Court 2010.

THE COURT: Okay. That's
certainly a good authority. Anything else?

24 MR. SHERRY: Yes. Just with

1 respect to 24(a), that doesn't -- that does
2 allow a certain overlap in -- sorry, that does
3 permit issues that are not in the main case.
4 24(a) simply requires a common issue. In fact,
5 that's true for B as well. I think it's
6 commonly the case that intervenor's interests --
7 intervenor's claims don't totally overlap with
8 the interested parties.

9 THE COURT: In terms of claims,
10 your claims don't overlap at all in terms of
11 claims that have a chance of going forward.

12 MR. SHERRY: They overlap in terms
13 of -- and I assume by that you're referring to
14 the state law claims?

15 THE COURT: Yes.

16 MR. SHERRY: They overlap in terms
17 of both common issues of law and fact with
18 respect to 24(b) and in terms of an interest
19 being at stake, which is the 24(a) rule.

20 THE COURT: Okay.

21 MR. SHERRY: And that's what's
22 required. And the last thing I wanted to
23 mention is Mr. Fleming mentioned the Hoots case.

24 THE COURT: Yes.

1 MR. SHERRY: The Hoots case is
2 distinct from the damages issue that I mentioned
3 before in that Hoots involved an intervenor and
4 an existing party who were seeking that the
5 exact same pile of money go to the same place,
6 which is distinct from the difference in damages
7 that are sought by Par and Takeda.

8 THE COURT: All right.

9 MR. SHERRY: And that's all, Your
10 Honor.

11 THE COURT: Okay. So I'm going to
12 take a brief recess and I'll be right back. All
13 right. Don't go anywhere. We'll be in recess.

14 (Short recess.)

1 in the litigation. In my opinion the interests
2 that Par has in the lawsuit that Takeda filed is
3 whether or not the contract permits Mylan to
4 launch. And in that regard, the interest is
5 perfectly well represented by Takeda, which also
6 does not -- which has the same interpretation of
7 the contract and has the same interests in not
8 having Mylan launch, so I don't think that I
9 should allow Par to intervene as a matter of
10 right. I note in -- I do note in regard to that
11 point, that -- and its Par's motion to
12 intervene, page 11, it concedes that Par and
13 Takeda are, quote, presently aligned in seeking
14 to adjoin the sale or marketing of Mylan's ANDA
15 products. So I deny it as a matter of right.

16 In terms of as a matter of
17 discretion under rule 24(b)1(B), there may be a
18 common question of law or fact relating to the
19 interpretation of this contract, but the central
20 consideration in exercising discretion is
21 whether allowing intervention will cause delay
22 or prejudice. And it seems to me that allowing
23 intervention will cause both delay and
24 prejudice. The delay simply because Par wants

1 to assert and it's the thrust of its case, are
2 additional claims which Takeda can't possibly
3 assert and prejudice because it's just going to
4 increase the overall cost of the litigation, as
5 Par has pointed out in its briefing and says
6 Takeda won't do in terms of discovery and trial.
7 And what's more is Mr. Sherry said something
8 today which, you know, hints at some day Par may
9 be, down the road may be suing Takeda or at
10 least will be thinking about it. So I don't
11 think it's a good idea to allow Par to intervene
12 in this case. If it turns out that Par files a
13 lawsuit in this district and I have jurisdiction
14 over it, you know, we can revisit the question
15 of whether or not there should be some
16 coordination between the two cases. But I'm not
17 going to allow them to intervene, so I'm going
18 to deny that motion.

19 All right. So preliminary
20 injunction, Mr. Fleming.

21 MR. FLEMING: Good morning again,
22 Your Honor. May I approach with some, some
23 slide materials?

24 THE COURT: Okay.

1 MR. FLEMING: And one other
2 housekeeping matter, Your Honor, before I start.
3 The parties did, in an attempt basically to
4 follow your guidance with respect to this whole
5 sealing and what's sealed and what can be
6 discussed and appreciating that Your Honor would
7 have probably have no view of us like trying to
8 seal the courtroom, we're not even asking that.

9 THE COURT: Good choice.

10 MR. FLEMING: So what we did was
11 we put together kind of a chart. May I approach
12 again?

13 THE COURT: This is like some code
14 so I'll understand what you're saying?

15 MR. FLEMING: Exactly, Your Honor.

16 THE COURT: Okay. I'm fine with
17 that. And honestly, I don't think the
18 particular dates and dollar figures, I doubt
19 that any of them actually matter, so I think you
20 can probably do this without ever actually
21 referring to this. What I'll call the Mylan
22 guest enter date, I got the general idea of when
23 that is. I think you can just call things
24 delay, whatever, I will basically understand,

1 but if you feel it necessary, go ahead.

2 MR. FLEMING: That's a very fair
3 comment, Your Honor. And you will notice when
4 we go through the slide, there are no code A,
5 code B or whatever. I deliberately left them
6 out and appreciating that you have read all the
7 briefs and you know basically all the things
8 we're talking about anyway. So I think we can
9 do that without the code and I also have
10 informed the court reporter that we are using
11 this type of code and that maybe a reference
12 here or there to a letter.

19 MR. FLEMING: Yes, Your Honor.
20 That's exactly what I plan to do.

21 THE COURT: And a little bit with
22 the irreparable harm, because I'm not convinced
23 that there actually is any irreparable harm to
24 Takeda here, which is essentially just because

1 there's a date in the future when these generics
2 are going to be entering the market and it seems
3 to me that in terms of -- and Mylan can
4 certainly pay any damages you can come up with
5 and that because, because of two reasons, one of
6 which is I already did this kind of analysis
7 for, coincidentally enough, your client in
8 Takeda versus West-Ward and so I expect that
9 this same data will come out in the future and
10 allow people who are more expert than me to
11 figure out what the damages are if Mylan is
12 wrongfully on the market. But in any event, why
13 don't you get to that second?

14 MR. FLEMING: I understand what
15 you're saying and we will get to irreparable
16 harm. And as you will appreciate as we go
17 through the slide, the focus mainly is the
18 likelihood of success and interpretation of
19 1.2(d). I am going to do a little background to
20 give the court a background as to what the
21 products at issue were and what the products
22 were in the Hikma case.

23 THE COURT: So, just tell me, Mr.
24 Fleming, because I've seen you multiple times

1 before and respect your abilities to do this
2 sort of thing, how long do you expect your
3 presentation to be?

4 MR. FLEMING: A little bit over 30
5 minutes, maybe.

6 THE COURT: That's good.

7 MR. FLEMING: Okay. Turning to
8 slide 1, we're here for a preliminary
9 injunction. As the Court appreciates, the legal
10 standard requires four factors and appreciating
11 what Your Honor just said, we are going to focus
12 on the reasonable likelihood of success on the
13 merits as well as try to change your mind with
14 respect to irreparable harm as to what harm
15 Takeda will suffer as a result of Mylan's breach
16 of 1.2(d) of the license agreement.

17 Slide 2, there are -- the four
18 points with respect to likelihood of success are
19 Mylan has launched its ANDA product without a
20 license from Takeda and is in breach of the
21 license agreement. The West-Ward litigation,
22 which is the Hikma case, we referred to both
23 ways, is exactly the case you were referring to
24 before, which did involve an injunction and the

1 accounting that you referenced. We do not
2 believe and hopefully will demonstrate to you
3 that the West-Ward litigation was not a 1.2(d)
4 trigger. Point number 3, we also hope to show
5 that, that Takeda and Mylan, when they settled
6 their underlying ANDA litigation, they did not
7 contemplate or intend the West-Ward litigation
8 to be a trigger with respect to this license.

9 THE COURT: Wouldn't that require
10 extrinsic evidence?

11 MR. FLEMING: No, Your Honor, I
12 don't believe it requires extrinsic or parole
13 evidence. I think looking within the four
14 corners of the license agreement, you will see
15 how not only the language of 1.2(d) doesn't
16 apply to Hikma, but you also see by looking at
17 the MFN provisions as well as all -- all the 1.2
18 factors, which are A through F, are all
19 predicated on an ANDA product being launched and
20 they're all predicated on the idea of a certain
21 time period that Mylan has to wait in relation
22 to what we call the first first. And that's
23 Par, Amneal and Watson. And so to the extent
24 that is in, and in the four pages, we believe

1 that not to be extrinsic evidence.

2 THE COURT: No, no, if it's in the
3 agreement, yeah, okay.

4 MR. FLEMING: So there's a slide
5 on that. And hopefully I can convince you. And
6 then the final point is from the license
7 agreement, it's clear that Mylan has admitted
8 that if they breached the agreement, that they
9 are infringing patents-in-suit. There's 17
10 orange book --

11 THE COURT: Presumably we're going
12 to concentrate on 2 and 3. I don't think we
13 need to say any more about 1 and 4.

14 MR. FLEMING: Okay. Done. Okay.
15 Next slide, slide 4, please. A little bit of
16 how we got here today, what the recent events
17 are. We learned on November 25 or it appears
18 from the FDA website that Mylan launched its
19 infringing ANDA product. On November 26th we're
20 aware of a first sale. On December 2nd we filed
21 our complaint in this case and on December 5th
22 we filed the present motion for preliminary
23 injunction. And I think it's interesting to
24 also point out that we were able to reach an

1 agreement between Mylan and Takeda to avoid
2 figure a TRO in this case with respect to
3 Mylan's sales and distribution of the ANDA
4 product.

5 THE COURT: And that speaks well
6 of the two sides working together, but that's
7 kind of irrelevant to my decision, right?

8 MR. FLEMING: Yes and no, Your
9 Honor. I think when we get to irreparable harm,
10 it will be a factor because to the extent Mylan
11 agreed to stop selling the product, what harm
12 are they going to have if you continue that?

13 THE COURT: I don't like to use
14 agreements that seem to me to be -- I mean, I'm
15 dubious on that one.

16 MR. FLEMING: Okay. Slide number
17 5, please. Little background with respect to
18 the original litigation. It was an ANDA
19 litigation. It was a litigation that involved
20 Mylan's ANDA. In October of 2016 Takeda filed a
21 complaint. The case was settled in November of
22 2017. The settlement was the settlement
23 agreement and licensing agreement that we're
24 talking about today. The license agreement

1 granted Mylan a non-exclusive license to market
2 the ANDA product. The generic entry dates are
3 the 1.2 dates that we're going to be talking
4 about in greater detail. As the Court is aware
5 1.2(a) is a set date. That date hasn't come
6 yet. There are additional triggering events.
7 1.2(b) through (f), our position is that none of
8 those triggering events have occurred and thus
9 Mylan's launch of an ANDA was in breach of at
10 least section 1.2 as well as 1.4, which is the
11 marketing provisions.

12 Next slide please. This is what I
13 just said. Flip to the next slide, please.
14 Takeda's Colcrys products, that's the product
15 Takeda sells, it's a brand product, it's
16 indicated for three indications, prophylaxis of
17 gout flares, treatment of gout flares and FMF,
18 which is a bloating in the stomach and other
19 areas of the body. It has a dose form of a
20 tablet and it was launched in September of 2009.

21 Next slide, please. The West-Ward
22 litigation. This is the case that Mylan
23 believes was the triggering events for the
24 summary judgment and in this case triggered

1 1.2(d).

2 Background on this case. This
3 case was originally filed in October 2014.
4 Important to note there were five patents that
5 were originally asserted in the case. Takeda
6 then asserted infringement of additional three
7 patents, so there were 8 patents asserted in the
8 case. During summary judgment briefing, which
9 was before Your Honor, the parties agreed to
10 dismiss with prejudice five of those patents.

11 THE COURT: Those were the five
12 original patents, right?

13 MR. FLEMING: No. There's a mix.
14 It's four original and one of the three. So
15 they are not all the original.

16 THE COURT: Okay.

17 MR. FLEMING: And I have a slide
18 that will show that to you.

19 THE COURT: No. I believe you.

20 MR. FLEMING: I think that's an
21 important point. And then the final point is
22 your summary judgment decision of December 2018
23 where this court held that three of those
24 patents were adjudicated to not be infringed

1 under the patents.

2 The next slide, please. Little
3 bit of background about Hikma's Mitigare
4 product. I think this is important because it
5 goes to whether the parties contemplated or
6 didn't contemplate this case being a final
7 decision pursuant to 1.2(d). The Hikma Mitigare
8 product was approved in September 2014. It was
9 a 505(b)2 product, i.e., it was not an ANDA
10 product. It was not a Colcrys ANDA. So unlike
11 the 10 other parties that are subject to
12 settlements with Takeda, they all filed ANDAs to
13 the Colcrys product, relying on the Colcrys
14 ANDA. That wasn't the case with Mitigare.
15 Important, Hikma launched Mitigare in October of
16 2014. Why is that important? It's important
17 that the product was on the market before and
18 during the Mylan litigation. It's on the market
19 today.

20 THE COURT: But there was an
21 injunction in the middle there.

22 MR. FLEMING: You've got me on
23 that one. I don't know that for sure. If you
24 say so.

1 THE COURT: Let me think about
2 this for a second. Yeah, that's the reason why
3 I had to -- yeah, I mean, Takeda ended up
4 posting a bond because they joined the Mitigare
5 product and I think that got reversed by the
6 federal circuit and then Mitigare launched. But
7 there was like a chunk of time when Mitigare was
8 off the market, I'm pretty sure.

9 MR. FLEMING: Okay. I'll confirm
10 that one way or the other when Mylan gets to
11 speak. Let's go to the next slide, please. So
12 I think it's important to note and compare the
13 Mitigare product with the Colcrys product.
14 Mitigare is another branded product. It's not
15 an ANDA product. It's branded. It has only one
16 indication, prophylaxis of gout flares. And
17 actually the Mitigare label specifically states
18 that you can't use Mitigare for acute treatment.
19 And as you may recall, the summary judgment
20 decision got into the whole induced infringement
21 and whether a doctor was prescribing or not
22 prescribing. It's a different prescribing than
23 Colcrys. It has different indications.
24 Importantly it has a different form. It's a

1 capsule versus a tablet and we'll see how the
2 agreement talks about tablets, not capsules, for
3 example. It was launched in October 2014 and
4 probably most importantly that Mitigare, as it
5 is not related to Colcrys, it's not AB rated.
6 It can't be substituted at the pharmacy. So
7 it's different, it's not -- and we would say not
8 subject to this license agreement.

9 The next slide, please. And this
10 is a little summary slide. It's the side by
11 side, same information, different dosage form,
12 different indications. Mitigare only has one
13 indication. Both products are brand products.
14 And again, Mitigare is not AB rated and not
15 substitutable at the pharmacy.

16 Slide 12, please. Next slide.

17 1.2(d), this is really what brings us here, Your
18 Honor. Let's look at the key words in this, in
19 this section. We need a final court decision.
20 That's defined as exhibit A. I don't think
21 there's any dispute that a final court decision
22 and the definition requires that there was no
23 further appeal. That's not in dispute.

24 THE COURT: Right.

1 MR. FLEMING: It goes on, a final
2 court decision, holding, i.e., a decision, that
3 all, all unexpired claims of the licensed
4 patents -- licensed patents are a defined term,
5 there's 17 of them -- that were asserted and
6 adjudicated against a third party are either not
7 infringed or any combination of not infringed
8 and invalid and unenforceable. This dispute, I
9 think in the most simple of terms, Your Honor,
10 comes down to when you say were asserted, are
11 you saying there were 8 patents asserted, which
12 is what we said, which there were 8 patents in
13 the case and only three patents were ultimately
14 adjudicated in your summary judgment. In a
15 nutshell that's pretty much most of the fight.

19 MR. FLEMING: Well, yes, claims of
20 patents. That one they're even more claims.

1 courts required, trimmed them down as you go
2 along?

3 MR. FLEMING: I don't want to be
4 kind of smart, but there are patents that only
5 have one claim, so the answer to your question
6 is yes, but you're exactly right that in this
7 day and age and even before Your Honor where
8 there are multiple patents being asserted and
9 multiple claims that the courts do encourage the
10 parties to reduce the number of claims. I think
11 you do have rights to every claim and that is a
12 property right and you probably do have the
13 right to assert each and every claim, but to the
14 extent courts have no interest --

15 THE COURT: In your
16 interpretation, barring the 1 or 2, because I
17 think I actually -- I think I had a case now
18 that you actually mentioned it, one asserted
19 patent, two claims, they were both asserted and
20 both asserted, so it's possible, but as a
21 practical matter -- as a practical matter, if
22 the interpretation you want to give to this,
23 which is any claim that was ever asserted also
24 has to be adjudicated, basically this is never

1 going to come into play, particularly where the
2 background is we know you've got 17 or 18
3 patents covering aspects of the possible
4 generics that could be introduced, right?

5 MR. FLEMING: Actually I'll give
6 you an example where it does come into play.
7 And we're going to talk about it later. If you
8 think of the situation where Your Honor is
9 aware, which an ANDA applicant serves a notice
10 letter, raises and says in the notice letter to
11 the brand company that our ANDA does not
12 infringe, let's say 10 patents. Okay? If the
13 brand company files a complaint within 45 days,
14 there is that automatic 30-month stay.

15 THE COURT: Yes.

16 MR. FLEMING: Okay. To resolve
17 that 30-month stay under the Hatch Waxman Act,
18 that generic has to resolve all asserted and get
19 an adjudication with respect to all those
20 patents. So in that case, yes, they have to
21 resolve all the claims, because if they want to
22 get out from under the 30-month stay they have
23 to resolve all those issues substantively.

24 THE COURT: That's adjudication,

1 that's for the FDA, right, because the FDA won't
2 approve it unless they have what you're talking
3 about, right?

4 MR. FLEMING: Right. The 30-month
5 stay. But this paragraph here, 1.2(d) is itself
6 part of generic launches, so what are we talking
7 about here? We're talking about a situation
8 where a generic perhaps can get out from under a
9 30-month stay, get out and launch. What are
10 these provisions supposed to do? They're
11 supposed to protect Mylan, so they agree to a
12 date in 1.2(a). These other provisions are to
13 protect Mylan that if something were to happen
14 or to change, change the landscape, a generic
15 getting out from -- getting permission to launch
16 their product. That is a change. And under
17 this, there is some language that's deleted with
18 the three dots at the beginning, but there is,
19 after a certain amount of period, Mylan would
20 get to go if that generic beat the 30-month
21 ANDA, 30-month statutory requirement. And to do
22 that they have to address all the asserted
23 claims. And we have the word here, right there,
24 all.

1 THE COURT: But it is the case
2 that for FDA -- maybe not for the 30-month, but
3 for -- I thought it was the FDA had to approve,
4 they wouldn't approve as long as the 30-month
5 stay was in play or until they got a final
6 judgment that perhaps adjudicated all the
7 claims, but dismissing them would count as
8 adjudicating them as opposed -- right?

9 MR. FLEMING: That's an
10 interesting point again, Your Honor. That did
11 change in December of 2016. That change,
12 though, only applies to ANDAs filed after, I
13 believe it's December 5, 2016. Interestingly
14 here, Mylan's ANDA was filed before and does not
15 apply to what you just described, a dismissal.
16 So that's why here, where we do have a dismissal
17 with prejudice, both Takeda dismissed with
18 prejudice as did Hikma. They voluntarily
19 dismissed their affirmative defense of non
20 infringement and invalidity. So you have a
21 dismissal. That dismissal does not count pre
22 December 2016 for ANDAs as an adjudication. So
23 what we have here is we have 8 patents asserted
24 and even more claims, but I'm just talking about

1 the patents. We have at least 8 patents
2 asserted, and only three patents were actually
3 adjudicated. And so if the Hikma decision is a
4 final decision, which we dispute anyway, even
5 under that construction, we don't think Hikma
6 meets a final court decision because with
7 respect to the five patents that were not --
8 were not adjudicated, those five patents,
9 there's no holding that either they're not
10 infringed or a combination of not infringed and
11 invalid. Silence. And so because of that, this
12 can't apply, we say.

13 THE COURT: But isn't it the
14 case -- let's assume you had 8 asserted patents
15 in the Hikma litigation, but there are only
16 three asserted and adjudicated pad events,
17 right?

18 MR. FLEMING: Correct. What about
19 this word all? All the patents that were
20 asserted had to have been adjudicated.

21 THE COURT: Well, all unexpired
22 claims that were asserted and adjudicated.
23 That's like that whole sentence or that whole
24 phrase makes sense, doesn't it.

1 MR. FLEMING: I know exactly where
2 you're going and that's actually one of Mylan's
3 arguments. I think the answer, what you're
4 trying to do, it's almost like -- I don't mean
5 this disrespectfully. It's like you're going to
6 the last chapter of the book. You're looking to
7 see what happened in the decision. The decision
8 was there was an adjudication of three patents.
9 Agreed. That decision, how many patents were
10 part of that decision? Oh, there were three,
11 because however many were asserted would have
12 been adjudicated because that's what the
13 decision says. If you do it that way, then the
14 word asserted and adjudicated, basically either
15 have the same meaning --

16 THE COURT: They don't have the
17 same meaning, they work together, but go ahead.

18 MR. FLEMING: Either have the same
19 meaning or the word asserted means nothing
20 because ultimately you're getting an
21 adjudication of the three patents.

22 THE COURT: So when you go on and
23 it says they're either not infringed or any
24 combination of not infringed and invalid or

1 unenforceable, does the little 1 not infringed
2 add anything to the second clause there?

3 MR. FLEMING: I think it's an or,
4 but I think what it's telling you is a final
5 adjudication.

6 THE COURT: No, no. So the second
7 clause is any combination of not infringed and
8 invalid or unenforceable. Isn't something where
9 all patents are not infringed a combination of
10 not infringed and invalid or unenforceable?

11 MR. FLEMING: If I'm understanding
12 you right, you can't infringe an invalid patent.

13 THE COURT: What I'm pulling out
14 or what I'm asking for you to comment on is
15 there's a certain amount of redundancy that goes
16 on in these things, right? So it says they're
17 either not infringed or any combination of not
18 infringed and invalid or unenforceable.

19 MR. FLEMING: No, they're
20 different. There's no redundancy. The
21 answer is not infringed means that all the
22 patents that were adjudicated were found to be
23 not infringed. That's what you did in the Hikma
24 case, you found that the three patents at issue

1 were not infringed.

2 THE COURT: And isn't that also a
3 combination of not infringed and invalid or
4 unenforceable where not infringed is all and
5 invalid or unenforceable is zero?

6 MR. FLEMING: Well, I would look
7 at it differently. I would say that one is one
8 hundred percent are infringed and two, you could
9 either have a combination wear 2a patent is not
10 infringed because you've been able to design
11 around and secondly, other patents were either
12 obvious or for some other basis invalid. So
13 what that, to my mind means, you either in one
14 get all of them as not infringed or in two, you
15 can either be not infringed or some other basis.
16 And the other other basis are invalidity or
17 enforceability. And it all goes back to the
18 Hatch Waxman idea where you have to check a box
19 for each of the asserted patents, for example,
20 my 30-month stay example. You have to check a
21 box next to each patent and you can either check
22 all infringed or you can do some infringed and
23 some invalid. But again, you have to get all of
24 them one way or the other. I think I see them

1 as different, Your Honor.

2 THE COURT: So I haven't seen this
3 too much, but could a generic bring a
4 declaratory judgment against a brand new
5 company?

6 MR. FLEMING: Yes, if they don't
7 get sued within 45 days they can bring a
8 declaratory judgment, but there would be no
9 30-month stay.

10 THE COURT: And when generic
11 brings a declaratory judgment, does the branded
12 company have to actually assert any claims?

13 MR. FLEMING: In the form of like
14 a counter claim?

15 THE COURT: Yeah.

16 MR. FLEMING: I don't know if they
17 have to. I guess they could give a covenant not
18 to sue or some other basis.

19 THE COURT: So let's assume they
20 didn't assert any counter claim and then the
21 generic one, they would have been adjudicated on
22 whatever the generic brought or the patents were
23 invalid presumably, would that be a scenario
24 where the asserted and the adjudicated would not

1 be exactly the same?

2 MR. FLEMING: It could be. But I
3 think here, I'm trying to say they're not the
4 same, they're different, asserted and
5 adjudicated and that they both have to be
6 present for this to be a final court decision
7 that would trigger this. And if again, in the
8 context of this is in 1.2, generic entry dates,
9 if we're looking for a situation that changes
10 the status quo and puts a new product out there
11 on the market, the generic would have to address
12 both the asserted patents and get an
13 adjudication with respect to those patents.
14 That's what gets them on the market and that's
15 what would change and perhaps give Mylan the
16 benefit of an earlier date than the date in
17 1.2(a) that they agreed to.

22 MR. FLEMING: They do, Your Honor.
23 And first of all, they give context of what 1.2
24 is all about. The section 1.2 is about generic

1 entry dates. It's the date when Mylan, with
2 permission, can go to market with their ANDA
3 product. This is what they agreed to when
4 settling the case. A, as we said, is a certain
5 date. The other provisions, for example -- do
6 you have a copy?

7 THE COURT: Yes, I do.

8 MR. FLEMING: Okay. So if I look
9 at 1.2(b), it's a commercial sale by a third
10 party other than the first filers, Par and --

11 THE COURT: By the way, in that
12 thing does generic equivalent, does that
13 essentially just mean generic?

14 MR. FLEMING: No, it's generic
15 equivalent to Colcrys, the ANDA that was the
16 subject of the litigation.

17 THE COURT: Okay. But in other
18 words, a generic equivalent doesn't include
19 Mitigare, right?

20 MR. FLEMING: That's exactly
21 right, Mitigare is not a generic equivalent.

22 THE COURT: Okay. All right.

23 MR. FLEMING: It's a brand product
24 and not AB rated to Colcrys. The important part

1 of B is on the second to last line is that it's
2 permitted and authorized. And so what is this
3 doing? This is if Takeda were to give a license
4 or permit another generic to go, then Mylan,
5 they should get to go within, you know, certain
6 amount of time. You know, again, the market
7 changed. Something entered the market. A new
8 generic Colcrys product.

12 MR. FLEMING: Yes. Let me address
13 that.

14 THE COURT: Okay.

15 MR. FLEMING: That's section 1.5
16 on page 5 of the agreement. And this is very
17 important, Your Honor, because the most favored
18 nation -- and again, looking within the four
19 corners of the license agreement, this talks
20 about whether Takeda could give a license or
21 permission -- it's three lines up from the
22 bottom of the page -- a license or permission to
23 a generic equivalent product. Again, so if
24 Takeda were to give a license to another generic

1 and put that generic out on the market, that may
2 be a triggering event. The most favored nation
3 clause says that Takeda can't give a better deal
4 to somebody than they gave to Mylan.

5 THE COURT: Well, I guess that's
6 what I was wondering about, the most favored
7 nation clause is -- doesn't that mean that if in
8 terms of 1.2(c) -- I'm sorry, 1.2(b), wouldn't
9 that mean that Takeda has breached the most
10 favored nation clause if you're permitted to
11 authorize some other generic other than the ones
12 that are accepted?

13 MR. FLEMING: I'm not sure it's a
14 breach. It's provided in the agreement that if
15 we were to give permission to another generic to
16 go, that would then mean that Mylan would get
17 the same benefit.

18 THE COURT: Okay. Because that's
19 not time delayed?

20 MR. FLEMING: Right.

21 THE COURT: So in other words,
22 they'd be treated equal?

23 MR. FLEMING: This is actually an
24 interesting point about the MFN. They talked

about the Hikma case and they're trying to read that summary judgment as being the triggering event. Let me give you this proposal. What if Takeda had settled the Hikma case and gave Hikma a royalty free license that they could go day one, any day they wanted? That license is not covered by 1.5 because Mitigare is not a generic product.

THE COURT: Right. I think --

10 MR. FLEMING: So Mylan, there was
11 no -- our position is that Hikma and Mitigare
12 were not part of this agreement at all. So how
13 can a situation where Takeda gives a license to
14 a party, Mitigare, Hikma, they go and that
15 license would not trigger. There's no 1.2
16 paragraph that would trigger that event.

17 THE COURT: Okay.

18 MR. FLEMING: And I think that
19 ties into the idea that Mitigare was launched
20 before being sold, is sold today. Mitigare has
21 been out there. Mitigare, the sale of Mitigare
22 did not change anything. It wasn't a change to
23 the status quo that would kick in a 1.2
24 accelerator. It's not a Colcrys ANDA product.

1 THE COURT: Yeah. That seems --
2 it's not an ANDA, certainly not based on ANDA,
3 so it's probably not an ANDA product. All
4 right. So I think I -- I think I understand
5 1.2(c). And are 1.2(e) -- and 1.2(e) is just
6 kind of a more complicated version of 1.2(c),
7 isn't it?

8 MR. FLEMING: Sorry?

13 MR. FLEMING: Well, 1.2(c) is,
14 again, has a certain time period, but again what
15 it does is it gives preference to Par, Watson
16 and Amneal.

22 MR. FLEMING: That's exactly
23 right. Something is happening in the generic
24 world. That's what we're saying 1.2 is all

1 about. It's the title, generic entry dates.
2 It's in the description. It refers to Mylan
3 selling their ANDA product. Something happening
4 in the generic world. Mitigare, the Hikma
5 decision is not part of that generic world.
6 Mitigare is a brand.

7 THE COURT: Yeah. Even though I
8 take it -- so, you know, (b) and (e) talk about,
9 they have the word generic in there somewhere.
10 Seeing these particular companies, so we know
11 what it's talking about. (D) doesn't have the
12 word generic in there anywhere, does it.

13 MR. FLEMING: Correct.

14 THE COURT: And (f), which I
15 haven't studied, but that seems to have the word
16 generic in it too, right?

17 MR. FLEMING: (F) goes to whether,
18 you know, you either grant or don't grant the
19 preliminary injunction and how that effects all
20 the other generics, yes.

21 THE COURT: Okay. So that's -- I
22 mean, do you make anything -- I mean, is there a
23 reason why -- why doesn't 1.2(d) refer to
24 generic if it's limited to generics.

1 MR. FLEMING: I think the intent
2 of the parties, which I think you have to
3 consider, was that this entire agreement is for
4 the ANDAs and Colcrys ANDAs. The only thing I
5 can say is that (d), like the other paragraphs
6 in 1.2, does have the same time period, that's
7 number of days. And that's the same giving
8 preference to the earlier first, which are Par,
9 Amneal and Watson, which are generic products.
10 I can't put a word in that's not there. So you
11 are correct, a word is not there. I think it
12 was clearly meant that it was to be for ANDA
13 applications. And I think when we talk about
14 asserted and adjudicated and we talk about how
15 that applies to Hatch Waxman, I think that again
16 shows the intent of the parties that asserted
17 and adjudicated meant that the parties were at
18 the time of negotiating putting this in as ANDA
19 related. And it's a triggering event for
20 Mylan's ANDA product.

THE COURT: Okay. What else do you got there, Mr. Fleming?

23 MR. FLEMING: Turning to slide 13.

THE COURT: We're going to need to

1 pick up the pace.

2 MR. FLEMING: Okay. If you ever
3 wanted to go back and look, you asked before
4 whether the original five and the three that
5 were added, were those the three that were
6 ultimately decided, if you compare the numbers,
7 the ones on the far right, one comes from the
8 original five and two come from the three that
9 were added. Okay. Turning to slide 14, and I
10 will pick up the pace. I think both parties
11 agree --

12 THE COURT: Yeah, yeah. Let's
13 skip that. I think I've got that.

14 MR. FLEMING: Okay. I think slide
15 15 is an important one because if you look at
16 the language of 1.2(d) on the left-hand side and
17 again, I want to focus on all in the patents
18 that were asserted and adjudicated, it's
19 interesting how Mylan has tried to rewrite 1.2
20 to get it down to just three patents. Instead
21 of just saying asserted, they, in our first
22 letter back in October they described the two --
23 three patents and then asserted. Then in
24 the subsequent briefing that's gone on before

1 Your Honor, they put in continued to assert,
2 ultimately asserted, ultimately chose to assert,
3 continue to assert. In our view they're trying
4 to rewrite 1.2 to get it to the three patents.
5 And if you look at slide 16, for example --

6 THE COURT: I got the idea. Let's
7 skip ahead to like slide 19. That seems to be
8 the same thing. A lot of slides here that
9 repeat themselves.

10 MR. FLEMING: Slide 18 for a
11 second. I mean, I think slide 18, it's telling,
12 because in their attempt to track the language
13 of 1.2, which we say they don't meet, they've
14 got the all, they make it bold, but then they
15 have to say ultimately chose to assert.

16 THE COURT: Mr. Fleming, I'm not
17 really very impressed by relying on how they
18 describe things in their brief as some evidence
19 of how I should interpret the contract. I mean,
20 you know, they're briefs. I just don't think it
21 matters what exactly they say in the briefs in
22 terms of, you know, it's not like rule 11 as to
23 what it means in the contract.

24 THE COURT: Okay. Slide 19, where

1 you want to go, slide 19, this kind of
2 summarizes our interpretation of 1.2(d). We
3 believe it means that all claims asserted must
4 be adjudicated to a decision holding either one,
5 not infringed or two, any combination of not
6 infringed and invalid. And for at least three
7 reasons the West-Ward litigation doesn't mean
8 that. Takeda asserted only 8 patents, but only
9 three of the asserted patents were found not
10 infringed.

11 THE COURT: And just to be clear,
12 because I think you've said this already once,
13 but if it were the case that there was some
14 generic that you had to sue in an ANDA and you
15 had asserted the 8 patents against them, and
16 then when I leaned on you, you dropped five of
17 them and went to trial one three of them and you
18 lost, you'd say no effect, right, because you
19 dropped five of them along the way?

20 MR. FLEMING: Hard to say no
21 effect.

22 THE COURT: Well, you'd say it
23 doesn't trigger the provision.

24 MR. FLEMING: I think you asked me

1 what happens in a court in a trial --

2 THE COURT: No, no, no. Mr.

3 Fleming, before we get to trial, through some
4 combination of charm or pressure I get you to
5 drop five of them so we only go to trial to
6 three of them, does that mean that no matter
7 what I do at the trial on three, I can say these
8 are the worst patents in history and they're not
9 infringed to boot and it has no impact -- it
10 doesn't trigger 1.2(d)?

11 MR. FLEMING: I think -- I guess
12 I'm not really sure how to answer that, because
13 I'm not sure in the sense that I think 1.2(d)
14 required that you both -- that the patents that
15 were asserted are adjudicated. And to the
16 extent 8 were asserted, only three were
17 adjudicated.

18 THE COURT: And by adjudicated,
19 you mean judge rules infringed, invalid, not
20 infringed, not invalid, something like that?
21 You don't mean we agree to dismiss it with
22 prejudice?

23 MR. FLEMING: I think that under
24 the rules that apply to this ANDA for Mylan,

1 that would not work. And I'll give you another
2 example. So for example, if you settled a case
3 and dropped patents in settlement, which is sort
4 of what you're asking or making reference to,
5 under the Hatch Waxman generics don't want just
6 a dismissal with prejudice, they want a
7 dismissal finding nobody infringes. And finding
8 invalidity. The generic brand would need to
9 agree to language that all claims are dismissed
10 and -- or found not infringed, invalid and
11 unenforceable. Yes, the generic would need that
12 language, all asserted and adjudicated to get
13 out from underneath the, for example, a 30-month
14 stay.

15 THE COURT: And I take it in
16 Hikma, because I granted summary judgment, I
17 don't know, was there a final judgment after
18 that?

19 MR. FLEMING: There was a final
20 decision.

21 THE COURT: And I take it whatever
22 that said -- what did it say about the five
23 patents that had been dropped?

24 MR. FLEMING: Nothing. The

1 patents were voluntarily dismissed, i.e., they
2 were never adjudicated. Maybe there's a claim
3 preclusion. There is no issue preclusion with
4 respect to claims of those patents. They're out
5 there.

6 THE COURT: Okay.

11 THE COURT: Right. If it was
12 within the 30-month stay.

13 MR. FLEMING: Correct.

14 THE COURT: Okay. All right.

15 MR. FLEMING: And I'm just going
16 maybe slide 20, again, this is where -- I've
17 already talked about the 30-month stay.
18 Actually slide 21 goes to the point that Hikma
19 the maker of Mitigare, they dismissed their
20 affirmative defenses of non-infringement,
21 invalid or enforceability for those five
22 patents. There was no adjudication on those
23 five patents.

24 THE COURT: Okay. I got that.

1 MR. FLEMING: Okay. Let's turn to
2 slide 25, please. And you asked me some
3 questions whether the -- about whether things
4 were either extrinsic evidence or parole
5 evidence with respect to what the license
6 agreement, how you can read it.

7

8 MR. FLEMING: And what we set
9 forth on this slide is ditch portions within the
10 license agreement which we believe helps
11 demonstrate that the agreement was directed to
12 Colcrys ANDA products. And you start with the
13 whereas clauses and they talk about tablets.
14 Colcrys is a tablet. The generic has to be a
15 tablet to be AB rated. Mitigare capsule not AB
16 rated, so different products. Also in the
17 whereas clauses, the purpose of the license
18 agreement was an opportunity for pro competitive
19 generic competition, for Colcrys. Mitigare is
20 not a generic to Colcrys. We've already talked
21 about the entry dates. We've talked about the
22 most favored nation and then the licensed
23 patents that also talks and makes reference to
24 ANDA.

1 I think slide 26 I can just give
2 half a second to. I think Your Honor is aware
3 and it was in the briefs that the agreement does
4 provide that the patents are valid, enforceable
5 and infringed. So I don't think there's a
6 dispute about that. I think Mylan's only
7 defense is they say there was no breach. But if
8 there was a breach, I think we're clear on that
9 and so I don't think we have to spend any time
10 on 27. We can skip 28 and let's turn to 29,
11 which is the irreparable harm.

12 THE COURT: Yep.

13 MR. FLEMING: Irreparable harm.
14 We have a license agreement here between Takeda
15 and Mylan where Takeda has agreed that a breach
16 of section 1.2 or 1.4 is irreparable harm. It's
17 in the agreement. And we do cite the TP Group
18 case, which is one of your cases, that's the
19 contractual stipulation as to irreparable harm
20 alone suffices to establish that that element,
21 for purposes of issuing an injunction. But if
22 you look at the next slide, slide 30, the actual
23 agreement on irreparable harm, which is the
24 section, portion highlighted, Mylan acknowledges

1 that marketing the Mylan ANDA product in breach
2 of paragraph 1.2 of the license agreement would
3 cause Takeda irreparable harm. We believe that
4 to be admission. But even more important, I
5 think, is the language above that, Your Honor,
6 where the parties, Mylan and Takeda agreed that
7 Takeda would be entitled to immediate injunctive
8 relief. That goes beyond even just admitting
9 irreparable harm. So if one was to consider the
10 agreement on irreparable harm to be a factor to
11 be considered, I think the fact that the parties
12 actually stated and made an affirmative
13 statement that Takeda would be entitled to
14 immediate injunctive relief, it almost creates
15 an estoppel. They've agreed to that and here we
16 are. So to the extent, I think this factor goes
17 in our favor.

1 MR. FLEMING: I think this
2 paragraph on its own states that there is
3 irreparable harm and I also think --

8 MR. FLEMING: If there's no
9 breach, correct.

10 THE COURT: So I'm just thinking
11 about it, and, you know, normally you look at
12 irreparable harm as kind of an independent
13 determination from whether there's a likelihood
14 of success on the merits. But here if you're
15 relying on this paragraph for the irreparable
16 harm, then you probably have to have a fairly --
17 it would seem to me that it's kind of -- it's
18 just combining the two separate things that are
19 normally separate into one and making it an all
20 or nothing on the basis of whether or not I
21 think there's a likelihood of success.

22 MR. FLEMING: I can see why you
23 come to that conclusion. That's why I got
24 another slide that follows that.

THE COURT: Okay.

2 MR. FLEMING: But I see your
3 point. Your point is, as I understand it, that
4 if there was no breach, then they're not
5 admitting to anything and they didn't admit that
6 there was any irreparable harm. To the extent
7 you're being asked to determine the likelihood
8 of success on that point, I guess if it's a
9 close call, for example, and you can understand
10 my interpretation of were asserted to mean 8
11 patents and that adjudicated were only three
12 patents, and you also understand -- it's three
13 and three, and it's a close call, I think that
14 this does become a factor because there is going
15 to be and there has been a launch of Mylan's
16 ANDA product. So the fact that they have
17 launched means that they have done something,
18 they have put a product out there and so that
19 fact, I think, gets you beyond, you know, just
20 the breaching, so I think there has been
21 irreparable harm.

22 THE COURT: Let me ask you a
23 slightly different question that's perhaps not
24 relevant to anything, but maybe it is. I take

1 it does the most favored nation clause prevent
2 you from having made -- does it prevent Takeda
3 from having made deals with the other generics
4 who are not Par and Watson and Amneal, that they
5 would have the same generic entry date as the
6 default?

7 MR. FLEMING: Actually that's an
8 interesting point. And I'm sorry, I missed the
9 beginning of your question, but if you're asking
10 the most favored nation is, hypothetically if
11 there is a most favored nations clause, what
12 that means is that the substance of agreements
13 cannot give a better deal.

14 THE COURT: But it can give you
15 the same deal?

16 MR. FLEMING: It can give you the
17 same deal, which is an interesting question in
18 the sense that we don't see any other generics
19 launching. That Hikma decision was back --

20 THE COURT: Well, I mean, I don't
21 think that's an argument really -- I mean, for
22 one thing, Mylan doesn't know what any other
23 generic agreed to, right?

24 MR. FLEMING: Correct.

1 THE COURT: Yeah, yeah, yeah, they
2 could make some educational guesses, but these
3 are all highly confidential agreements so
4 whatever -- secret, not secret from your side,
5 but a secret from their side.

6 MR. FLEMING: Disagree a little
7 bit. That most favored nation clause they have,
8 that tells you that if there are other generic
9 entry things, they've got to be at least the
10 same.

11 THE COURT: This can't be better?

12 MR. FLEMING: Correct.

13 THE COURT: Yeah, yeah, I got
14 that.

15 MR. FLEMING: Slide 31, we've
16 already spoken to this, but we believe these to
17 be additional irreparable harm. I just heard
18 what you said about the market and that Mylan
19 can pay whatever the damages are and how much is
20 sold, et cetera, but I think there is harm that
21 you can't put a price tag on. And to the
22 extent, as we just discussed, Takeda has settled
23 with 10 other generics, their actions have the
24 potential to open the door for all of them at

1 different times, some faster than others.

2 THE COURT: But presumably the
3 default date would open the door just down the
4 road, right?

5 MR. FLEMING: The default date
6 does open the door, yes, to generic. That's
7 part of settling the cases, that there is a date
8 certain that there will be full generic
9 competition for this product. The agreement,
10 though, does provide that Par, Amneal and Watson
11 get a better deal. They're first filers.
12 What's happening here is Mylan is trying to jump
13 ahead. They're using almost like a gotcha, that
14 this Hikma decision somehow puts them ahead of
15 Par, Amneal and Watson.

16 THE COURT: Or maybe they're not
17 so much saying it puts them ahead, but they're
18 the first one to realize they can take advantage
19 of it, right? Maybe they've got some clever
20 lawyers.

21 MR. FLEMING: Okay. Mr. Sommers
22 might like that when he gets here, but that
23 could be one way to interpret it, yes.

24 THE COURT: All right. Is there

1 anything else there, Mr. Fleming. I think I've
2 given you plenty of time here, and I am
3 interested in having this finish before lunch,
4 so why don't I hear from the opposition.

5 MR. FLEMING: Yes, Your Honor.

6 THE COURT: All right. So you are
7 Mr. Sommer?

8 MR. SOMMER: I am, Judge. Nice to
9 appear before you.

10 THE COURT: You look kind of
11 familiar, but I can't place you as someone I've
12 actually had before me before. Is this the
13 first time?

14 MR. SOMMER: It is the first time,
15 Your Honor, although I was trying to figure out
16 if our mutual 10 years at our respective U.S.
17 Attorney's Office may have brought us in
18 contact, but I couldn't think of a time either
19 because I will admit when I looked you up, you
20 looked familiar to me as well.

21 THE COURT: That's because we're
22 generic.

23 MR. SOMMER: Judge, just to give
24 you a sense, my argument subject to your

1 questions will take about 20 minutes. I hope my
2 estimate will be better than Mr. Fleming's. To
3 answer one of your questions, this is a question
4 of law and that's because the language in the
5 contract is clear and unambiguous. The license
6 agreement at issue in this case grants to Mylan
7 the right to market and sell its generic
8 Colchicine product as of a specific date, using
9 our little code sheet, that's letter B, or at an
10 earlier date if any of certain events or
11 circumstances occur. And one such circumstance,
12 as the Court well knows from all the briefs you
13 received, is set forth in section 1.2(d) of the
14 license agreement which expressly permits Mylan
15 to market and sell its generic product a
16 specified number of days after the language you
17 have seen and had read to you several times.
18 And as Your Honor also knows, in December 2018
19 this court granted summary judgment to Hikma in
20 the West-Ward case, holding that Hikma did not
21 infringe the three and only three licensed
22 patents that were both asserted and adjudicated
23 in that litigation. Now, to be clear, as you've
24 heard, there were five others that were asserted

1 earlier in that litigation, but before briefing
2 was completed, and again, it may have been Your
3 Honor's persuasive suggestions, but before
4 briefing was completed on Hikma's summary
5 judgment motion, Takeda voluntarily dismissed
6 with prejudice its claims as to five of those
7 patents.

8 THE COURT: Yeah, you know, my
9 memory is a little hazy on that, but I think
10 what the federal circuit had held pretty much
11 indicated that those five patents, that there
12 was some reason why they couldn't really be
13 asserted any more in good faith. Wasn't just
14 they wanted to make my life easier.

15 MR. SOMMER: Maybe the federal
16 circuit was more persuasive in that regard.

17 THE COURT: They can be pretty
18 persuasive.

19 MR. SOMMER: Yes. In any event,
20 as I noted, Your Honor then did adjudicate those
21 three patents and held that as to the only three
22 license patents that were both asserted and
23 adjudicated, that Hikma had not infringed those
24 patents. That's the relevant background here.

1 There was an agreement negotiated between Takeda
2 and Mylan, two sophisticated parties with able
3 counsel containing clear and unambiguous
4 language. And that language expressly permits
5 Mylan to launch based on the Hikma litigation.
6 Your decision was in December 2018. Takeda did
7 not appeal. Became a final decision. After the
8 required time period passed, Mylan provided
9 notice to Takeda that it was going to launch.

10 THE COURT: And so December of
11 2018 decision, the required time was probably 30
12 days because there was no notice of appeal,
13 right?

14 MR. SOMMER: Right.

15 THE COURT: So that's late January
16 or sometime in January of 2019?

17 MR. SOMMER: There's no dispute on
18 the number of days having run.

19 THE COURT: No, no. But my point
20 really was the days ran and then some.

21 MR. SOMMER: Yes.

22 THE COURT: And was Mylan's
23 eventual entry, was that limited by when the FDA
24 approved it.

1 MR. SOMMER: That was certainly
2 one aspect. There were certainly unrelated
3 aspects to this litigation, but Mylan certainly
4 made sure it waited the allotted period of time
5 and had FDA approval before its launch.

6 THE COURT: Okay.

7 MR. SOMMER: So here we are judge
8 on a motion for preliminary injunction brought
9 by Takeda in which Takeda is arguing that it
10 really didn't intend to give Mylan this right to
11 launch and where Takeda is arguing that you
12 should rewrite the contract to deprive Mylan of
13 an express contractual right and prevent Mylan
14 from providing the market with a lower cost
15 Colchicine product. And of course for them to
16 prevail, Judge, as you well know, they first and
17 foremost must establish a likelihood of success
18 on the merits. And that means in this case that
19 they must establish that the contract doesn't
20 sat what it clearly does say.

1 MR. SOMMER: I don't believe so,
2 Your Honor, but if I may hand up one
3 demonstrative because I think it goes directly
4 on that point.

5 THE COURT: Sure.

6 MR. SOMMER: I've marked this as
7 Mylan exhibit 2. And this really picks up. I
8 do want to -- I do want to address asserted and
9 adjudicated, but let me jump to this because it
10 really was a focus of much of your questioning
11 to Mr. Fleming. What I've put on this
12 screenshot, Your Honor, are the relevant
13 sections of section 1.2.

14 THE COURT: Yes.

15 MR. SOMMER: And Your Honor, I
16 mean, you really took some of my best material
17 in your questions, but as you'll already
18 observe, 1.2(b) has the words generic equivalent
19 and that's defined in exhibit A as an AB rated
20 equivalent. 1.2(e) has the authorized generic
21 language, same. 1.2(f) has the same language,
22 generic equivalent, but there are other sections
23 and Takeda's counsel studiously avoided 1.2(g),
24 for example. It's not like the parties somehow

1 forgot to put generic equivalent in 1.2(d).
2 It's also not in 1.2(g). And why? Because
3 1.2(d) and 1.2(g) are litigation-based triggers.
4 They're about the patents. They're patent
5 centric is probably the best way to describe it.
6 Whereas 1.2(b), (e) and (f) are product centric.
7 It is not nonsensical and unreasonable to
8 believe that these two sophisticated parties
9 didn't understand what they were writing in the
10 contract. If 1.2(d) was supposed to be limited
11 to an ANDA, as Mr. Fleming keeps urging Your
12 Honor to somehow draft onto the contract, it
13 simply would have said that. And it's not an
14 isolated event, judge, which is why I thought it
15 was important to put before you 1.2(g), which
16 Mr. Fleming never mentioned. And that's why,
17 Judge, I come back to the point of contract
18 interpretation, because both parties here agree
19 that the language is clear and unambiguous.
20 What is the starting point for the Court. Well,
21 the Delaware courts make that clear, you are
22 constrained by a combination of the parties'
23 words and the plain meaning of those words and
24 the launching point is the four corners of the

1 contract. And here, and this is a quote, when
2 two sophisticated parties bargain at arm's
3 length and enter into a contract, closed quote,
4 as is certainly the case here, quote, the
5 presumption is even stronger that the contract's
6 language should guide the court's
7 interpretation. That's the JFD Steel Work case,
8 this district, from 2011. So look, we can all
9 read the words.

10 So where do we diverge here?

11 Well, Takeda takes the position that the patents
12 originally asserted in the Hikma action, but
13 then voluntarily dismissed, somehow remained
14 asserted. And as we explained in our opposition
15 brief, this is nonsensical. While they may have
16 at one point asserted eight license patents,
17 immediately upon the filing of their stipulation
18 of dismissal, which was their own choice, maybe
19 influenced by the federal circuit, its claims
20 with respect to five of those patents were no
21 longer asserted. That's precisely what a
22 stipulation of a voluntary dismissal is by a
23 plaintiff, it's a decision by the plaintiff to
24 abandon asserted claims to make claims that were

1 ones asserted no longer asserted. And as a
2 result there were only three claims that were
3 asserted that required adjudication. And I
4 should add, Your Honor, you brought it up in
5 your summary judgment decision. You recognized
6 this. You wrote about the Takeda had asserted
7 eight patents, but then quote, Takeda
8 voluntarily dismissed its infringement claims
9 with respect to five, quote, thus only three
10 patents remain at issue.

11 THE COURT: You know, it's coming
12 back to me. I think the way it went, because I
13 could be wrong about this, but Hikma filed in
14 its opening brief there was all eight of them.
15 Only when Takeda responded they said oh, by the
16 way, we're dropping five of them. I think it
17 was -- not that I think it makes any particular
18 difference for here, but I think it was, you
19 know, it was just un-defensible to keep going
20 forward with those five.

21 MR. SOMMER: And that may very
22 well be, Judge, and I agree with you it doesn't
23 make a difference here. Because again, we get
24 to the word adjudicated. Our position is look,

1 those eight asserted, the five are no longer
2 asserted.

3 THE COURT: So one of the
4 questions -- one of the things that the
5 plaintiff wrote in its brief that I'm interested
6 in your response to is they said asserted and
7 adjudicated makes the asserted essentially
8 meaningless because whether it gets adjudicated
9 or things are asserted.

10 MR. SOMMER: I actually scribbled
11 in my notes while I was listening another
12 instance where you actually anticipated my
13 argument. The word asserted, you put your
14 finger right on it. It's against third parties.
15 It's against third parties. Takeda is in
16 control of the claims it asserts against third
17 parties in litigations. The language of section
18 1.2(d) is limited to situations where Takeda
19 chooses to put its licensed patents at issue by
20 asserting claims with respect to them. It chose
21 to sue Hikma. It chose to assert the license
22 patents. It didn't need to, but it elected to
23 do so. And why? All of these slides, trying to
24 argue that Mitigare and Colcrys are different.

1 I'm going to avoid using the wrong adjective.
2 It's nonsense, Judge. And the reason is first,
3 they're both .6 milligram Colchicine products.
4 They both cover some of the same things. Yes,
5 one is a capsule, one is a tablet, but what
6 speaks the most about it is what Takeda did. As
7 soon as there was this threat of Mitigare,
8 Takeda took action. It filed its action. It
9 pursued that for two years. And Judge, in its
10 own brief in that case, in support of its
11 preliminary injunction, Takeda argued, quote,
12 Hikma's release of a Colchicine products,
13 Mitigare, thus would have a devastating and
14 permanent effect on Takeda sales of Colcrys.
15 For them to stand here now today after having
16 argued how they're essentially the identical
17 drug and Mitigare was this incredibly giant
18 competitor to Colcrys, I think is a little
19 insincere.

20 THE COURT: Yeah. Well, you know,
21 you know, I don't think, you know. Great
22 respect to Mr. Fleming, so I don't think it's
23 being insincere here, but as a party Takeda has
24 already been to this court once saying the sky

1 is falling and turned out it wasn't. And then
2 when I do the damages, you know, then their
3 position was nothing to see here, this was a
4 minor blip. So, you know, I don't think they're
5 the only pharmaceutical company in the history
6 to do 180 on a position when it suited their
7 purposes, but it does -- its something that I
8 can't put out of my head.

9 MR. SOMMER: Judge, let me turn to
10 the next reason why they have no likelihood of
11 success on the merits. And that's the word
12 adjudicated, because what the contract makes
13 clear hear, the relevant provision is, quote, a
14 final court decision, holding that, all claims
15 to the license patents that were asserted and
16 adjudicated against the third party are not
17 infringed or a combination. Now, in their
18 opening brief they actually tried to mount an
19 argument that all eight were adjudicated. I'm
20 sure you picked that up. They were saying, oh,
21 yeah, it is adjudicated, it might be claim
22 preclusion but not issue preclusion, but they're
23 all adjudicated. We explained in our opposition
24 brief that was certainly wrong. I'm not going

1 to --

2 THE COURT: Well, but I think Mr.
3 Fleming has a point or he might have a point, I
4 don't know, because I haven't researched it,
5 that adjudicated, you know, the FDA or the ANDA
6 statute, somewhere in there, they have or they
7 either do or have had some strange rules about
8 things so that what might be considered to be
9 adjudicated for one purpose might be different
10 for a different purpose.

11 MR. SOMMER: That may be, but it's
12 not an issue any more before you because in
13 their reply brief they did what you just
14 described as a 180 and now their position is it
15 wasn't adjudicated. That's their position on
16 reply and certainly Mr. Fleming's position in
17 his argument to Your Honor this morning. They
18 are now arguing that the way you should
19 interpret the language is that whenever claims
20 are asserted must have been adjudicated. That's
21 now their formulation, because their whole
22 argument is well, there were eight so -- but
23 only three were adjudicated, so the trigger does
24 not get implicated. That's not the language in

1 the agreement. The language is asserted and
2 adjudicated. So the language was a total change
3 in position.

4 THE COURT: And I'm sorry, what
5 was the answer to the question of whether
6 asserted is a necessary word, you know, when I
7 asked that, you then went into 1.2(d) and
8 1.2(g), but the argument that it's surplusage,
9 what's the response?

10 MR. SOMMER: I made the same
11 point, Your Honor, under the language of 1.2(d),
12 it's within Takeda's control whether they assert
13 the patents. So if you look at 1.2(d) --

14 THE COURT: But I can't adjudicate
15 for patents whose claims are not asserted,
16 right?

17 MR. SOMMER: That was my example
18 in my outline. It's a declaratory judgment
19 brought by another party, that's not a claim
20 asserted by Takeda. And Mr. Fleming actually
21 agreed with Your Honor, so that formulation of
22 language actually gives Takeda the power to
23 decide for itself whether to assert claims or
24 not, so it doesn't make it surplusage. It

1 actually has significant meaning for Takeda. It
2 can protect its patents by not asserting the
3 claim if it so chooses. That's its right, but
4 it doesn't change the clear and unambiguous
5 language of what is there. And again, I don't
6 want to beat the dead horse of sophisticated
7 parties, but as you saw from the document I
8 handed up, the sophisticated parties here agreed
9 to a particular way of describing the triggers.
10 And here, 1.2(d) has nothing to do with some
11 product, some drug. It's based on a patent
12 centric result. What happened with the patents
13 that were asserted and adjudicated. So where
14 does that leave them? It leaves them with
15 argument --

16 THE COURT: Just, Mr. Sommer, just
17 to play out what I think you're saying here.
18 Dividing it into product triggers and licensed
19 patent triggers, the way this would be sort of
20 connected together is in some ways protecting
21 Mylan's interests if there's some generic
22 version that's launched ahead of schedule so to
23 speak or through some way and then Mylan would
24 have the delay, but they get to launch because

1 the other company launching is going to cause
2 them to lose sales sooner or later. And in
3 other words with the licenses, it's kind of --
4 if the licensed patents aren't good enough to
5 keep out competitors because they're adjudicated
6 against Takeda, then, then Mylan ought to get to
7 rush in because everyone else is going to be
8 able to rush in too if the patents can't protect
9 the product.

10 MR. SOMMER: Well, I can't speak
11 to what others would have the right to do
12 because we have not seen those contracts nor
13 have they been presented to this court, which is
14 why I keep hearing about them and then in the
15 next breath they're not relying on extrinsic
16 evidence, I can't really reconcile the two. But
17 certainly the contract Mylan negotiated with
18 Takeda does allow Mylan to launch in that
19 circumstance, where the license patents that
20 were asserted and adjudicated are found to be
21 non-infringing or the combination.

22 And Judge, just one last thing on
23 this. Who says we get put ahead? No one says
24 we get put ahead. There's a number of days we

1 have to wait there. And whose to say that what
2 they call the earlier filers don't have the
3 right to immediately enter and still get ahead
4 of us for that fixed number of days? Now, I
5 could be accused of speculating here, I think
6 it's common sense, but certainly Takeda, the
7 movant on this motion who bears the burden of
8 proof, has not come forward with those license
9 agreements to show that there's any scenario
10 under which Myland gets ahead of the earlier
11 filers. There's no record on that at all. And
12 I think I can use common sense and go, I bet, I
13 bet those don't have that period of time they
14 have to wait. And that keeps us behind the
15 earlier filers. So there's no record that
16 supports this idea that we're jumping.

17 THE COURT: You say it keeps you
18 behind, and yet you've launched and they
19 haven't.

20 MR. SOMMER: Maybe you're right.
21 Maybe we do have smarter lawyers. I don't take
22 credit, but the other lawyers at my table are
23 very smart. Look, I don't know what their
24 contracts say. Maybe the 1.2(d) in some of the

1 other license agreements say authorized generic.
2 I don't know. We negotiated a contract. We
3 have rights under the contract. And where do
4 they end up once you look at the plain meeting
5 of asserted and adjudicated? It's all the
6 balance of their arguments basically saying
7 well, that wasn't our intent, which is code for,
8 Judge, please rewrite the contract. That is
9 particularly inappropriate in a preliminary
10 injunction motion.

11 THE COURT: Well, so Mr. Sommer, I
12 would say -- I mean, one of the things that is
13 sort of -- I guess I would put it like this, and
14 I asked you to comment on it. You know, you've
15 said the two parties here are sophisticated,
16 large pharmaceutical companies. All these other
17 generics that are floating around are also and
18 the -- and from what's been said, I gather that
19 Mylan is a second filer, not a first filer, and
20 in terms of interpreting the contract, shouldn't
21 I be aware of sort of the surrounding business
22 model of this industry, which is, you know,
23 barring malpractice, the contracts are written
24 to -- so that the first filers get to go first

1 and the second filers go after?

2 MR. SOMMER: Right. But you know,
3 Judge, from the many cases you have had that the
4 first filer doesn't necessarily go first. Maybe
5 they don't have FDA approval yet, maybe they're
6 not ready from a manufacturing perspective.

7 I've been involved in cases where the first
8 filer didn't get to go first. Now, I don't
9 know. Again, this is all extrinsic evidence.
10 It's not before the court. But there certainly
11 are scenarios where that is a possibility. And
12 again, as I'm saying here, there's nothing in
13 this license agreement that provides for Mylan
14 to go first that eliminates the possibility that
15 the earlier filers could go first if they had
16 product, if they had FDA approval.

17 And so, you know, getting back to
18 really my final point here, which is in several
19 parts, I don't want to mislead, Your Honor.
20 They're asking you to rewrite the contract.
21 They want you to inject words into 1.2(d) that
22 are not there. And, you know, to his credit,
23 Mr. Fleming essentially acknowledged that. He
24 stood before you and said, you asked the

1 question, you know, you acknowledged that
2 authorized generic, those words aren't there,
3 and he goes yeah, they're not there. And your
4 follow up was, it's your argument that they
5 should have been there. And he sheepishly or
6 reluctantly acknowledged that. They shouldn't
7 be there. That's not the negotiation that was
8 made and it's certainly not some kind of
9 drafting error. I don't know if that's what
10 they're arguing. So the starting point, as I
11 mentioned before if you look at the words of the
12 contract, I've given you my demonstrative. I
13 think it makes it clear what's really going on
14 here. That's why their arguments about Mitigare
15 are so misplaced, because they're belied by the
16 plain language of section 1.2(d) which by itself
17 terms did not include the limiting language
18 Takeda now urges you to add.

19 Let's see. I made that argument
20 already. Okay. I briefly addressed the
21 similarity in the drug, so I don't need to go
22 into that. So, you know, this reliance on
23 extrinsic evidence that you see throughout
24 Takeda's briefs about what Mylan was thinking,

1 what the parties intended, you know, it
2 shouldn't be considered by the Court,
3 particularly here where the language is so
4 clear.

5 I want to address one thing about
6 this 30-month stay argument that I heard a
7 little bit about. First of all, there was no
8 30-month stay in the Hikma case because it was
9 not a Hatch Waxman case.

10 THE COURT: Right.

11 MR. SOMMER: Let's take the
12 hypothetical they're trying to create that this
13 would make no sense if Mylan somehow is allowed
14 to launch but the litigating party is still
15 subject to a 30-month stay. It's a red herring,
16 Judge. Let me explain why. Let's use Hikma as
17 an example, even though there was no 30-month
18 stay there. What actually happened? Takeda
19 dismisses as to five patents. The remaining
20 three are adjudicated against them. Under that
21 scenario, if that was a Hatch Waxman case, the
22 generic would be freed of the 30-month stay and
23 get to launch and under our license agreement so
24 would Mylan, so that's not their theoretical

1 concern, because both can launch. Of course
2 Mylan would have to wait the prescribed number
3 of days. Let's change the facts a bit. Assume
4 that Takeda voluntarily dismisses all eight of
5 its patents. I think you were actually moving
6 toward that question in your discussion with Mr.
7 Fleming. Again, the 30-month stay would be
8 lifted as to the generic. That's the effect of
9 them dismissing that litigation. It's lifted.
10 In that situation, 1.2(d) is not triggered.
11 Mylan cannot launch because there was no
12 adjudication. So this theory of theirs, how
13 could there be a scenario where Mylan gets to
14 launch but the litigating party doesn't. It's
15 the null set. There's no scenario where that
16 happens. That actually confirms our
17 interpretation of the contract.

18 So, Judge, the bottom line is, I
19 know you understand our arguments because you
20 asked the questions that made that clear to me.
21 Takeda's argument that you should rewrite the
22 license agreement to add language that clearly
23 was not intended to be in 1.2(d) should be
24 rejected. This section says what it says, it

1 says what the parties negotiated and agreed it
2 would say and that is that if Takeda claims that
3 are both asserted and adjudicated result in a
4 holding of non-infringement or combination of
5 non-infringement, invalidity or
6 unenforceability, Mylan is allowed to launch
7 after waiting the set number of days and that is
8 just what came to pass here.

9 Let me very briefly address
10 irreparable harm, if I may.

11 THE COURT: Sure.

12 MR. SOMMER: Your Honor, if you
13 find Takeda has failed to carry its burden of
14 demonstrating a likelihood of success on the
15 merits, that's really the end of it. I think
16 you're right. I mean, they've hitched their
17 horse on the wagon of -- their irreparable harm
18 horse is hitched to the wagon of we have
19 supposedly breached. And that, in the absence
20 of us breaching, there has been no showing of
21 irreparable harm by Takeda. I mean, their only
22 argument is, look at section 110 of the
23 contract, which has the language. We're not
24 running away from what the contract says. I

1 want to make that clear. We stand by it, but --

2 THE COURT: So if I think there is
3 a likelihood of success that's been shown, does
4 that mean then you agree irreparable harm?

5 MR. SOMMER: Well, Judge, let me
6 put it this way. I'm not trying to avoid your
7 question. This court, in the Cabellas versus
8 Hybee case and other courts in this district,
9 have found that just because the parties
10 stipulate to irreparable harm doesn't divest the
11 Court of the discretion to make a finding.

12 THE COURT: Yeah, I don't want to
13 say something about Cabellas that's wrong, but
14 on the one hand you have multi-million dollar
15 corporation and on the other hand you have a
16 bunch of individuals, so it's not quite the same
17 thing.

18 MR. SOMMER: I didn't want to be
19 so presumptuous as to tell you the parties have
20 effectively tied your hands. What I will say is
21 we stand by our contract, we stand by the clear
22 and unambiguous language in the contract. All
23 I'm pointing out, Judge, is if we didn't breach,
24 there's been no showing of irreparable harm

1 whatsoever.

2 And I want to just comment very
3 briefly on slide 31, which Mr. Fleming put
4 before you, I think to try to make the argument
5 that even if you find there was no breach, they
6 somehow have established irreparable harm
7 separate and apart from section 110. And I was
8 intrigued by the second and third bullet point
9 on that slide. The second bullet point says
10 Mylan's premature launch will subvert the intent
11 of the other 10 Colcrys ANDA settlements.

12 Really? Says who? They're not in evidence
13 before Your Honor. It's totally extrinsic.
14 Shouldn't be considered. And then bullet point

15 3 --

16 THE COURT: Well, it would be okay
17 if it were extrinsic, but I think, as you say,
18 there's no actual evidence of what those
19 settlements are.

20 MR. SOMMER: Right. I think you
21 said it better than me, Judge. And then the
22 third bullet point, this assertion that there
23 would be permanent and non-recoverable loss of
24 market share and price erosion, again, there has

1 been no showing of that by Takeda whatsoever in
2 its papers. In fairness, they did attach I
3 think one -- was it Takeda attached one letter
4 from a customer, an e-mail? I think there was
5 one, so there was something, but certainly did
6 not establish to any extent price erosion and
7 loss of market share.

8 THE COURT: Okay. Is that all,
9 Mr. Sommer?

10 MR. SOMMER: If you could just
11 give me 10 seconds just quickly flip through
12 what else I dragged up here. Oh, if I may,
13 Judge, I know you already told Mr. Fleming that
14 you weren't going to be persuaded by it, but
15 this, on slide 4, the chronology at the very end
16 where they pointed out that we agreed to a
17 stipulation to avoid a TRO, I just want to tell
18 you two things; one is I guess no good deed goes
19 unpunished, but more importantly, it was an
20 extremely limited agreement. If you look at our
21 secret code sheet, letter F identifies when that
22 period of time expires.

23 THE COURT: Yeah, I saw that in
24 the briefing.

1 MR. SOMMER: I just didn't want
2 you to think it was some indeterminant period of
3 time.

4 THE COURT: I appreciate you're
5 pointing that out and I really do think in this
6 particular case avoiding a TRO application is I
7 like to phrase a good deed. So yeah, whatever I
8 decide I'm not going to use that against you.

9 MR. SOMMER: I think that's all I
10 have, Judge. Thank you.

11 THE COURT: Mr. Fleming, briefly.

12 MR. FLEMING: Very briefly, Your
13 Honor. I'd like to address quickly the document
14 that was handed up by Mr. Sommers. I think
15 1.2(d) and 1.2(g) are very different. 1.2(d)
16 does talk about products. You can't not
17 infringe something that's not a product. So
18 1.2(d) definitely goes to a product. And 1.2(g)
19 talks about patents can invalid. And I think
20 everyone would agree that if the patents are
21 invalid, there is no license for any patent. So
22 I don't think you have to specify anything with
23 respect to that. So I think arguing that 1.2(d)
24 is not product related is inaccurate. I will

1 note that when you specifically asked Mr. Sommer
2 whether there was any reference in the
3 settlement or license agreement to Mitigare or
4 to Hikma, there's none. He didn't point to
5 anything, Your Honor. And it's not there. And
6 the reason it's not there is because the
7 parties' intent, which Your Honor is supposed to
8 consider, and it's part of every contract --

9 THE COURT: But I'm supposed to
10 consider based on what's in the agreement,
11 right? I mean, what the agreement tells me the
12 parties' intent is?

13 MR. FLEMING: Right. So
14 everything in the agreement points to Colcrys
15 and Colcrys ANDA products and generics that make
16 Colcrys ANDA products. That's everything in the
17 agreement and he's gone beyond the agreement.
18 And he accused me of rewriting 1.2(d) but I
19 think he's rewriting it. And we've looked at
20 those slides. There was a question about a DJ
21 and what aD J -- well, if a generic made a DJ to
22 Takeda, that wouldn't be a third party case
23 anyway. That's not a third party decision.

24 THE COURT: You're saying because

1 the party brought it against Takeda, Takeda is
2 not a third party, that's what you're saying?

3 MR. FLEMING: Right. Yes.

4 THE COURT: I understand Takeda is
5 not a third party, but the generic who brought
6 it, they're a third party.

7 MR. FLEMING: Okay.

8 THE COURT: Aren't they?

9 MR. FLEMING: You're right. And
10 then one last point, Your Honor. With respect
11 to the example that Mr. Sommers made about
12 Hikma --

13 THE COURT: Let me just get
14 something straight here. According to what's
15 written down here, I think he's Mr. Sommer.

16 MR. FLEMING: I'm sorry.

17 THE COURT: Is that right?

18 MR. SOMMER: Yes.

19 MR. FLEMING: I'm sorry. Mr.
20 Sommer. This is the first time I met Mr.
21 Sommer, so I apologize. So with respect to his
22 assertions that in the Hikma case if Hikma was a
23 generic, which it's not, and whether he went to
24 eight patents and five were dropped or not

1 adjudicated, whether that would permit them to
2 launch or get rid of the 30-month, it definitely
3 would not. They need a determination. Hikma
4 would have needed a determination on all eight
5 patents. The dismissal with prejudice --

6 THE COURT: And that is to launch
7 before the 30 months is up, right?

8 MR. FLEMING: Correct. And be a
9 triggering event. That was the purpose and a
10 reasonable interpretation of 1.2(d). That was
11 to address a generic launching within a 30-month
12 period or being available to them. And that
13 would then trigger and permit Mylan to get
14 either equal footing or an advanced launch date.

15 THE COURT: Is there any reference
16 in the 40 pages of agreement to the 30 months?

17 MR. FLEMING: There are multiple
18 references to the Hatch Waxman act, but there's
19 no specific -- the words 30 month are not there.

20 THE COURT: Okay.

21 MR. FLEMING: Thank you, You
22 Honor.

23 MR. SOMMER: Judge, two sentences
24 from the table, if I could.

THE COURT: All right.

Mr. Sommer: Just want to point out two things. The Hikma case was not a Hatch Waxman case, so no 30-month stay.

THE COURT: Got that.

MR. SOMMER: And then finally on that it says nothing about Mitigare in the contract, it does talk about licensed patents and Takeda asserted those licensed patents in the Mitigare case.

THE COURT: Okay. All right. So thank you. I did think -- and I'm not going to issue a decision right now, but I do think the argument has sharpened up really the -- that really the issue is, you know, probability of success on the merits and it very much boils down to this 1.2(d) paragraph as informed by the rest of the contract and with the date that you've given the code of F to in mind, if that's -- it's not going to be long before I have a decision and -- and if I have a decision that's favorable to Mylan, does this date code F, is that sort of the first date that Mylan can do anything or its actually -- actually I think

1 I saw this, it's like my decision or the date,
2 whichever comes first?

3 MR. SOMMER: Correct, Your Honor.

4 THE COURT: Okay. All right. I
5 think it's pretty much the case that if I had a
6 decision that was favorable to Mylan, I would
7 probably stay it for some short period of time,
8 maybe 7 days so that people could run to the
9 federal circuit and give them at least a chance
10 to think whether that's something that they want
11 to give themselves more time to consider or not.
12 Do you have any comment on that, Mr. Sommer?

13 MR. SOMMER: No.

14 THE COURT: Okay. All right.

15 Well, thank you very much. I've enjoyed the
16 arguments and we'll be in recess.

17 (End at 12:31 p.m.)

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1 State of Delaware)
2 New Castle County)

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CERTIFICATE OF REPORTER

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I, Stacy M. Ingram, Certified Court Reporter
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13

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/s/ Stacy M. Ingram

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